

November 6, 2015

366867

RECEIVED
OPPT CBIC

2015 NOV -9 AM 10:21

Via Federal Express

TSCA Confidential Business Information Center (7407M)
WJC East – Room 6428
Attn: TSCA Section 8(e) Coordinator
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Re: TSCA Section 8(e) Submission

Dear Sir or Madam:

[REDACTED] is hereby submitting to the U.S. Environmental Protection Agency (EPA) under section 8(e) of the Toxic Substances Control Act (TSCA) information [REDACTED] conducted on the following substances:

Chemical Name	CASRN	On Public TSCA Inventory?
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Dimethylactamide	35123-06-9	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Ethylformate	109-94-4	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED] has not made a determination at this time as to whether a substantial risk or injury to human health or the environment is, in fact, presented by this information. Indeed, most of the subject substances are not manufactured, imported, processed, or distributed by [REDACTED] in the U.S. Further, for many of the testing substances the observed effects were unremarkable. However, as a matter of good product stewardship, [REDACTED] is submitting this information to the Agency in accordance with EPA's TSCA section 8(e) guidance

We trust that the Agency finds this information useful. Please note that a confidential version of this letter is enclosed wherein the company and information are treated as Confidential Business Information (CBI). A TSCA 8(e) Substantiation of Confidentiality Questionnaire is included in Attachment 2. If you have any questions or need additional information regarding this submission, please do not hesitate to contact me at [REDACTED].

Sincerely,

[REDACTED]

[REDACTED]

Attachment 1 - Summary of Results

Attachment 2 - CBI Substantiation (CBI)



Attachment 1

Summary of Results

1 SUMMARY

The purpose of this study was to [REDACTED]

Each group consisted of [REDACTED] as follows:

Test Item: [REDACTED]

Group 5: dimethylactamide

Group 7: ethylformate

Dose Levels: [REDACTED]

A standard dose volume of 5 mL/kg body weight with a daily adjustment to the actual body weight was used.

1.1 Maternal Data

Mortality and General Tolerability

All females survived until the scheduled necropsy

Bedding in the mouth was observed in one female [REDACTED] and in all females in [REDACTED] during the treatment period. This was considered to be a sign of discomfort rather than a toxic effect of the test item.

No further clinical signs were observed in any female in any dose group.

Food Consumption and Body Weights

In group [REDACTED] food consumption was statistically significantly reduced at the start of treatment over days 6 - 9 p.c. Body weight gain was statistically significantly reduced

[REDACTED]

from day 8 p.c. until the end of the study. Corrected body weight gain was reduced without statistical significance.

In group 5 (dimethylactamide), mean food consumption was lower than in the control group throughout the study and was statistically significantly reduced over days 6 - 9 p.c. Body weight gain was statistically significantly reduced over days 8 - 16 and 18 - 21 p.c. Corrected body weight gain was reduced without statistical significance.

In groups [REDACTED] food consumption was slightly reduced on days 6 - 9 p.c. and was not affected by treatment with the test item thereafter. This initial reduction was considered to be a slight, non-adverse effect of the test item.

In [REDACTED] mean food consumption was statistically significantly reduced over days 6 - 9 and 9 - 12 p.c. and remained lower throughout the rest of the treatment period. Body weight gain was statistically significantly reduced on days 1 and 7 - 15 p.c. Corrected body weight gain was reduced without statistical significance.

Reproduction Data

In all groups receiving the test item, no test item-related findings were observed in the relevant reproduction data (post-implantation loss, the number of fetuses per dam and the weights of the fetuses).

Macroscopical Findings

At necropsy, no findings were observed in any female in any group.

1.2 Fetal Data

External Abnormalities and Variations

No test item-related findings were observed in any litter in any group.

Sex Ratios

The sex ratios of the fetuses were not affected by treatment with the test item in any group.

Body Weights

In [REDACTED] the weights of the fetuses were statistically significantly reduced in both the male and female fetuses and were outside the range of the historical control data. This reduction was considered to be a test item-related effect.

In groups [REDACTED] fetal weights were not affected by treatment with the test item

Visceral Abnormalities and Variations

Visceral examination of fetuses in [REDACTED] did not reveal any test item-related findings.

Bone and Cartilage Abnormalities and Variations

In [REDACTED], there was an increased incidence of zygomatic arch fusion in the skull. It could not be excluded that this was due to the treatment with the test item.

In [REDACTED] (dimethylactamide), there was a slightly increased incidence of zygomatic arch fusion. It could not be excluded that this developmental delay was due to the treatment with the test item.

In [REDACTED] there was an increased incidence of malpositioned pelvic girdle. It could not be excluded that this was a test item-related effect.

In [REDACTED], there was an increased incidence of zygomatic arch fusion in the skull. It could not be excluded that this developmental delay was due to the treatment with the test item.

Ossification and Supernumerary Ribs

In [REDACTED] there was a slightly increased incidence of non-ossified cervical vertebral bodies and supernumerary ribs.

In [REDACTED] there was an increased incidence of non-ossified cervical vertebral bodies and digits of the limbs.

Additional Cartilage Variations

In [REDACTED], there was a slightly increased incidence of a small hole in the cartilaginous skull structures.

In [REDACTED] there was a slightly increased incidence of branched costal cartilage.

1.3 Conclusion

In [REDACTED] bedding in the mouth was observed in one female. No other test item-related effects were observed.

In [REDACTED], bedding in the mouth was observed in all females. Food consumption, body weight, body weight gain and corrected body weight gain were reduced. The weights of the fetuses were reduced in both the males and [REDACTED]

[REDACTED]

females and were outside the range of the historical control data. There was an increased incidence of zygomatic arch fusion in the skull and a slightly increased incidence of non-ossified cervical vertebral bodies and supernumerary ribs in the fetuses.

In [REDACTED] no test item-related effects were observed.

In [REDACTED] (dimethylactamide, 300 mg/kg body weight/day), mean food consumption, body weight gain and corrected body weight gain were reduced. At skeletal examination of the fetuses, there was a slightly increased incidence of zygomatic arch fusion.

In [REDACTED], there was an increased incidence of malpositioned pelvic girdle in the fetuses as well as non-ossified cervical vertebral bodies and digits of the limbs. There was a slightly increased incidence of a small hole in the cartilaginous skull structures.

In [REDACTED] (ethylformate, 100 mg/kg body weight/day), mean food consumption was slightly reduced on days 6 - 9 p.c. and was not affected by treatment with the test item thereafter.

In [REDACTED] mean food consumption was slightly reduced on days 6 - 9 p.c. and was not affected by treatment with the test item thereafter. There was an increased incidence in the fetuses of zygomatic arch fusion in the skull and a slightly increased incidence of a small hole in the cartilaginous skull structures.

In [REDACTED] mean food consumption, body weight gain and corrected body weight gain were reduced. There was an increased incidence of zygomatic arch fusion in the skull of the fetuses and a slightly increased incidence of branched costal cartilage.

In [REDACTED], no test item-related effects were observed.

5 DISCUSSION AND CONCLUSION

[REDACTED]

All females survived until the scheduled necropsy. No macroscopical findings were observed in any dose group. Reproduction was not affected by any test item.

In [REDACTED] bedding in the mouth was observed in one female. No effects on food consumption or body weight were observed. The weights of the fetuses were not affected by treatment with the test item. No test item-related effects were observed in the fetuses.

In [REDACTED] bedding in the mouth was observed in all females. Food consumption was statistically significantly reduced at the start of treatment. Body weight gain was statistically significantly reduced for most of the study and corrected body weight gain was reduced without statistical significance. The weights of the fetuses were statistically significantly reduced in both the males and females and were outside the range of the historical control data. There was an increased incidence of zygomatic arch fusion in the skull and a slightly increased incidence of non-ossified cervical vertebral bodies and supernumerary ribs in the fetuses.

In [REDACTED], no effects on food consumption or body weight were observed. The weights of the fetuses were not affected by treatment with the test item. No test item-related effects were observed in the fetuses.

In [REDACTED] (dimethylactamide, 300 mg/kg body weight/day), mean food consumption was lower than in the control group throughout the study and was statistically significantly reduced over days 6 - 9 p.c. Body weight gain was statistically significantly reduced during most of the study. Corrected body weight gain was reduced without statistical significance. The weights of the fetuses were not affected by treatment with the test item. No test item-related findings were observed during visceral examination of the fetuses. At skeletal examination, there was a slightly increased incidence of zygomatic arch fusion.

In [REDACTED], no effects on food consumption or body weight were observed. The weights of the fetuses were not affected by treatment with the test item. There was an increased incidence of malpositioned pelvic girdle as well as non-ossified cervical vertebral bodies and digits of the limbs. There was a slightly increased incidence of a small hole in the cartilaginous skull structures.

In [REDACTED] thylformate, 100 mg/kg body weight/day), mean food consumption was slightly reduced on days 6 - 9 p.c. and was not affected by treatment with the test item thereafter. No effects on body weight were observed. The weights of the fetuses were not affected by treatment

[REDACTED]

[REDACTED]

with the test item. No test item-related findings were observed during skeletal examination of the fetuses.

In [REDACTED], mean food consumption was slightly reduced on days 6 - 9 p.c. and was not affected by treatment with the test item thereafter. No effects on body weight were observed. The weights of the fetuses were not affected by treatment with the test item. There was an increased incidence of zygomatic arch fusion in the skull and a slightly increased incidence of a small hole in the cartilaginous skull structures.

In [REDACTED], mean food consumption was statistically significantly reduced at the start of treatment and remained lower throughout the rest of the treatment period. Body weight gain was occasionally statistically significantly reduced. Corrected body weight gain was reduced without statistical significance. The weights of the fetuses were not affected by treatment with the test item. There was an increased incidence of zygomatic arch fusion in the skull and a slightly increased incidence of branched costal cartilage.

In [REDACTED] no effects on food consumption or body weight were observed. The weights of the fetuses were not affected by treatment with the test item. No test item-related findings were observed during skeletal examination of the fetuses.

Based on this study [REDACTED] and [REDACTED] were shown to be clear of effects on reproduction and on the skeletal development and stage of ossification.



Attachment 2

TSCA 8(e) Substantiation of Confidentiality

- (1) Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.*

On its own behalf, the Company provides the following substantiation of its claims to hold confidential the information that has been redacted from this submission under section 8(e) of the Toxic Substances Control Act (TSCA) (15 U.S.C. § 2607(e)).

- (2) For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.*

The information claimed as confidential should be held confidential indefinitely, *i.e.*, until this technology is obsolete, or until the information is widely known. As discussed below, disclosure prior to this time could result in commercial detriment and impairment of EPA to obtain such submissions in the future.

- (3) Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.*

The Company has never disclosed the confidential business information in any filing with EPA or other government agencies and is not including confidential business information in the description of the health and safety study it is submitting today. To the best of our knowledge, no Federal agency or court has ruled on the confidentiality of this information, nor has the Company disclosed the information as part of a health and safety study to any other Federal agency.

- (4) Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.*

The Company securely guards the information claimed as confidential by not disclosing the identity or uses of the chemicals that is the subject of the health and safety studies reported today. Employees are under a duty to protect the confidentiality of this information. To prevent undesired disclosure by employees who leave the Company, we require that such employees sign an agreement prohibiting disclosure of this and other confidential business information.

(5) If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

This information has been held strictly confidential and has not been disclosed to persons outside of the Company, except as part of confidential and privileged communications with outside legal counsel and under non-disclosure agreements with third parties when such parties need to know such information. Future disclosures will be similarly restricted. Further, only those employees within the Company with a need-to-know obtain this information.

(6) Does the information claimed as confidential appear or is it referred to in any of the following: a) advertising or promotional material for the chemical substance or the resulting end product; b) material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale); c) professional or trade publications; or d) any other media or publications available to the public or to your competitors. If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

The information claimed as confidential does not appear in advertising or promotional materials, safety data sheets or other similar materials, professional or trade publications, or any other media available to the public or competitors.

(7) Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

No.

(8) Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors' access to your customers. Address each piece of information claimed CBI separately.

Disclosure of the information claimed as confidential would likely result in substantial harm to the Company's competitive position. Currently, the public cannot connect the information claimed as confidential to the company.

- (9) *Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?*

[REDACTED]

- (10) *Is this substance/product commercially available and if so, for how long has it been available on the commercial market? If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.? If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established. What is the substance used for and what type of product(s) does it appear in?*

To the best of our knowledge [REDACTED]

[REDACTED] Two substances are on the non-confidential TSCA Inventory. One of these substances (CASRN 109-94-4) is in commerce in the U.S. and is primarily used as an industrial solvent. It is not known whether the other substance (CASRN 35123-06-9) is in commerce in the U.S.

- (11) *Describe whether a competitor could employ reverse engineering to identically recreate the substance.*

While the substances could be reverse engineered, disclosure of the information claimed as confidential would likely result in substantial harm to the Company's competitive position by revealing business strategy and allow competitors to save research and developmental time and costs, thereby giving them an unfair advantage in the market and curtailing the motivation to develop new technology.

- (12) *Do you assert that disclosure of this information you are claiming CBI would reveal: a) confidential processes used in manufacturing the substance; b) if a mixture, the actual portions of the substance in the mixture; or c) information unrelated to the effects of the substance on human health or the environment? If your answer to any of the above questions is yes, explain how such information would be revealed.*

Disclosure of the information that is claimed as confidential would reveal commercial information unrelated to the effects of the substances on human health or the environment. Disclosure of the information claimed as confidential would reveal business strategy. The

company name and the uses of the substances do not indicate the substances' effects on human health or the environment.

- (13) *Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.*



- (14) *Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.*

No.